4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0795]

Agency Information Collection Activities; Proposed Collection; Comment Request; A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed study entitled "A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising."

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-0795 for "Agency Information Collection Activities; Proposed Collection; Comment Request; A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising

OMB Control Number 0910-NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research, which includes links to the latest *Federal Register* notices and peer-reviewed publications produced by our office.

Direct-to-consumer (DTC) prescription drug advertising may make quantitative claims about the drug's efficacy or risks (Ref. 1). Although there is research and FDA guidance ("Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional

Labeling and Advertisements," available at https://www.fda.gov/media/117573/download) that provides general guidelines for how to present quantitative information, it is not fully understood how consumers will interpret specific quantitative claims. We conducted a literature review and found that while some types of quantitative information are well-studied (e.g., relative frequencies), many questions remain on how best to communicate certain quantitative information about prescription drugs. For example, we do not have sufficient information about how consumers interpret different claims describing medians (e.g., "People treated with Drug X lived for a median of 8 months" alone or in combination with a definition such as "In people receiving Drug X, this means that about half lived more than 8 months and about half lived less than 8 months" or "A median is the middle number in a group of numbers ordered from smallest to largest"). This study aims to survey U.S. adults about their interpretation of specific quantitative claims.

We plan to use an address-based, mixed-mode methodology that will direct one randomly chosen member of sampled households to complete a 20-minute online survey, with nonrespondents receiving a paper questionnaire. The sample will be representative of the U.S. population. A sample of U.S. households will be drawn from the U.S. Postal Service Computerized Delivery Sequence File. Adults aged 18 or over will be eligible for participation. Up to four contacts (mailings) will be sent to respondents by U.S. mail. The contacts will include the URL for the online survey and a unique survey login. This unique survey login will be used to track completed surveys without the use of personally identifying information. The contact method, based on recent recommendations (Ref. 2), includes a prenotification letter (week 1), a web survey invitation letter (soft launch in week 2, full launch in week 3), a reminder postcard sent to nonresponders (week 5), and a final mailing with the paper version of the survey sent to nonresponders (Week 7). We estimate a 40-percent response rate, based on recent experience with similar surveys. We estimate 1,100 respondents will complete the main study (see table 1).

Based on previous research (Refs. 3, 4, and 5), we plan to include a small prepaid incentive in the second mailing sent to the sampled addresses as a gesture to encourage response and maintain data quality. We expect that approximately 5 percent of the sampled addresses will be postal nondeliverable returned letters from the first mailing (prenotification letter), so the second mailing is estimated to go out to the remaining addresses. We also will conduct an experiment to assess the efficacy of using a promised post-paid incentive. Seventy-five percent of the sample will be sent the promised incentive upon completion of the survey, and the remaining 25 percent of the sample will not be notified of or provided with any promised incentive. We opted to split the sample 75-25 rather than 50-50 because the initial evidence shows the benefits of including a promised incentive (Refs. 4, 6, and 7), and we aimed to maximize response rates.

The survey contains questions about respondents' perceptions and understanding of several quantitative claims drawn from DTC ads in the marketplace. We will also measure other potentially important variables, such as demographics and numeracy. The survey questions will be informed by consumer feedback elicited in one-on-one interviews (approved under OMB control number 0910-0847). The survey is available upon request from DTCResearch@fda.hhs.gov.

We will test whether any variables differed between modes (online versus mail survey) and will account for any mode effects in our analyses. We will examine the descriptive statistics for the survey items (e.g., frequencies and percentages) and explore the relationship between the survey items and demographic and health characteristics. We will weight the data to account for different probability of selection and nonresponse.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

Read prenotification letter	2,993	1	2,993	0.08 (5 min.)	239
Read web survey invitation letter[2]	2,843	1	2,843	0.08 (5 min.)	227
Read reminder postcard	2,585	1	2,585	0.03 (2 min.)	78
Respond to survey (web and paper)	1,100	1	1,100	0.33 (20 min.)	363
Total					907

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The numbers assume around 5 percent postal nondeliverables from the prenotification letter and estimates nonrespondents for the subsequent mailings.

References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*1. Sullivan, H.W., K.J. Aikin, and L.B. Squiers, "Quantitative Information on Oncology Prescription Drug Websites," *Journal of Cancer Education* vol. 33, Issue 2, pp. 371–374, 2018. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5334459/)

2. Dillman, D.A., J.D. Smyth, and L.M. Christian, *Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method, 4th ed.,* John Wiley & Sons, Inc.: Hoboken, NJ, 2014.

*3. Cheung, Y.T.D., X. Weng, M.P. Wang, et al., "Effect of Prepaid and Promised Financial Incentive on Follow-Up Survey Response in Cigarette Smokers: A Randomized

Controlled Trial," *BMC Medical Research Methodology*, vol. 19, Article 138, 2019. (https://link.springer.com/article/10.1186/s12874-019-0786-9)

4. Mercer, A., A. Caporaso, D. Cantor, et al., "How Much Gets You How Much? Monetary Incentives and Response Rates in Household Surveys," *Public Opinion Quarterly*, vol. 79, pp. 105–129, 2015.

5. Sun, H., J. Newsome, J. McNulty, et al., "What Works, What Doesn't? Three Studies Designed to Improve Survey Response," *Field Methods*, vol. 32, Issue 3, pp. 235–252, 2020. (https://doi.org/10.1177/1525822X20915464)

6. Ellis, J., J. Charbonnier, C. Lowenstein, et al., "Assessing the Impacts of Different Incentives and Use of Postal Mail on Response Rates," *American Association for Public Opinion Research (AAPOR) Conference*, Chicago, IL, 2022, May.

*7. Yu, S., H.E. Alper, A.M. Nguyen, et al., "The Effectiveness of a Monetary Incentive Offer on Survey Response Rates and Response Completeness in a Longitudinal Study," *BMC Medical Research Methodology*, vol. 17, Article 77, 2017. (https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-017-0353-1)

Dated: April 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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